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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/026,188

12/21/2001

Charles S. Zuker

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

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ALAMEDA, CA 94501

EXAMINER

ULM, JOHN D

ART UNIT

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/026,188	Applicant(s) ZUKER ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 4-9 12 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1) Claims 1, 4 to 9, 12 and 14 to 19 are pending in the instant application. Claims 1, 12 and 17 have been amended as requested by Applicant in the correspondence filed 28 April of 2008.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April of 2008 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5) Claims 1, 4 to 9, 12 and 14 to 19 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant claims are drawn to a "method for identifying a

compound that modulates taste signaling in taste cells” wherein that method identifies compounds that produce a “functional effect” upon a putative ion channel protein subunit identified in the instant specification as “TC-ICS”. The method lacks utility because the protein described therein has not been demonstrated to be operative in a specifically disclosed context and instant application does not disclose an established biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

The text on page 1 of the specification states that “[t]he taste cell-specific ion channel subunits that are specifically expressed in taste cells can thus be used to screen for modulators of taste cell function and to control taste perception”. The identification of "modulators of taste cell function" is not a specific utility. An example of an assertion of a specific utility can be found in the third and fourth paragraphs in column 10 of the Margolskee et al. patent (7,364,876), which contains the assertion that compounds that activate the TRP8 channel protein described therein induce the perception of a bitter taste whereas compounds that prevent the activation of TRP8 by a bitter tastant can be used to inhibit the perception of bitter taste. No such specific and substantial assertion appears to be present in the instant application as filed.

It is clear from the instant specification that the putative ion channel subunit protein described therein as “TC-ICS” is what is referred to as an "orphan ion channel" in the art. This is a protein whose cDNA has been identified because it encodes an amino acid sequence that is similar to that of one or more known ion channel subunit proteins. There is little doubt that, after complete characterization, a protein of the

instant invention may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. Whereas the determination that a protein of the instant invention is selectively expressed in taste cells suggests that it may play a role in the sensation of one or more taste modalities, a precise role in the perception of one or more specific taste modalities is not disclosed in the specification.

Further, the instant specification has failed to disclose a method that has been shown to demonstrate functionality for a putative ion channel subunit protein of the instant invention. It is fairly well known in the art that, whereas some ion channel subunits are capable of forming functional homomeric ion channel complexes, others only function when expressed in combination with related subunits with which they form heteromeric ion channels. At the time that the instant application was filed, the ability of the "TC-ICS" protein of the instant to form a functional ion channel has yet to be established. Therefore, the instant specification leaves it to the artisan to engage in the further experimentation that is needed to discover if "TC-ICS" is capable of functioning as a homomeric ion channel complex and, if so, to then to establish a nexus between the ability of a compound to effect the activity of that channel complex and the effect of that compound upon the perception of one or more taste modalities.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the

Art Unit: 1649

absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

In that decision, the court held that it is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research and experimentation when that research is needed to establish or reasonably confirm a practical utility for the claimed invention. Since additional experimentation is clearly needed to ascertain the conditions under which the activity of a "TC-ICS" protein of the instant invention can be measured and then to establish a nexus between the effect of a compound upon a measurable "TC-ICS" activity and the effect of that compound upon a specific taste modality, the claimed method does not have a practical utility in currently available form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1649

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6) Claims 1, 4 to 9, 12 and 14 to 19 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7) Claims 1, 4 to 9, 12 and 14 to 17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Margolskee et al. patent (7,364,876). Every element of the instant claims is disclosed in the section of Margolskee et al. entitled "5.5.

SCREENING ASSAYS FOR DRUGS AND OTHER CHEMICAL COMPOUNDS

USEFUL IN REGULATION OF TASTE PERCEPTION". In addition, the amino acid sequence presented in SEQ ID NO:2 of Margolskee et al. is identical SEQ ID NO:5 of the instant application and SEQ ID NO:4 of Margolskee et al. patent is identical to SEQ ID NO:8 of the instant application.

The Declaration by Charles S. Zuker and Yifeng Zhang filed on 02 May of 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the references.

The following is an excerpt from M.P.E.P. 2138.05:

"CLAIMED INVENTION IS NOT ACTUALLY REDUCED TO PRACTICE UNLESS THERE IS A KNOWN UTILITY

Utility for the invention must be known at the time of the reduction to practice. Wiesner v. Weigert , 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); Azar v. Burns , 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to practice unless the composition and the product produced by the method have a practical utility); Ciric v. Flanigen , 185 USPQ 103, 105 - 6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); Engelhardt v. Judd , 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); Rey - Bellet v. Engelhardt, 181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." Bindra v. Kelly , 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense

of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.)."

The evidence provided by that declaration and the instant specification fails to show that Applicant had established a practical utility for a "TC-ICS" protein of the instant invention or the functionality of that protein in a specific context at the time that the instant application was filed. In contrast, the Margolskee et al. patent had demonstrated functionality for the TRP8 protein described therein and established a specific role for that protein in the perception of bitter tastants.

Response to Arguments

8) Applicant's arguments filed 28 April of 2008 have been fully considered but they are not persuasive. Applicant urges that "[t]he application, in fact, teaches not only functional effects of TC-ICS activity (e.g., changes in membrane potential), but also its role in taste signaling". No, it doesn't. The instant application contains **unsubstantiated** assertions that "TC-ICS" activity can be measured by various methods identified therein but fails to provide any actual evidence of operability. Applicant is advised that a statement of a specific utility is treated as true if it would be believed to be true by one of ordinary skill in the art given the evidence of record. In so far as the specification allegedly discloses a role for "TC-ICS" is taste signaling, the assertion that it modulates taste signaling in taste cells has not been established by any experimental evidence and lacks the specificity required to support a practical utility

Because there is absolutely no evidence provided by the instant specification that the "TC-ICS" is capable of functioning as monomer or that a compound that activates "TC-ICS" has a specific effect upon the perception of a particular taste modality, the assertions contained in the instant are not credible to one of ordinary skill in the art of receptor biology in view of the evidence of record, or more precisely, the lack thereof. The mere fact that a protein of the instant invention is structurally related to known ion channel subunits and is expressed in tissue associated with taste perception does not support the conclusion that it is capable of functioning as a monomer or that it has a specific role in the perception of a particular taste. "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions", (M.P.E.P. 2106.02 II(b)(1)(ii)).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649